FOOD AND DRUG ADMINISTRATION

PUBLIC HEARING

Substances Prohibited From Use in Animal Food or Feed

Animal Proteins Prohibited in Ruminant Feed

TRANSCRIPT OF PROCEEDINGS OF PUBLIC HEARING

The Public Hearing concerning Substances Prohibited From Use in Animal Food or Feed and Animal Proteins Prohibited in Ruminant Feed commenced at 9:00 a.m. on the 30th day of October, 2001, at the Century Ballroom, Westin Crown Center Hotel, One Pershing Road, Kansas City, Missouri.

PANEL MEMBERS: Dr. Murray Lumpkin
(Presiding Officer)
Dr. Kathleen Akin,
Dr. Delia Parham,
Dr. Stephen Sundlof,
Dr. Stephen Solomon,
Dr. Dan Machesney

INDEX OF SPEAKERS

DR. LUMPKIN: I would like to call this Part 15 hearing to order, if I could. Everyone who wishes to be part of the audience, please be in their places.

I am Murray Lumpkin. I'm the acting deputy commissioner of the FDA, and I will be the presiding officer at this particular public hearing.

I would first like to thank each and every one of you for taking time out of your schedules to be with us today to have this opportunity for us and our colleagues from the Department of Agriculture to hear your comments, to hear your concerns, to hear your thoughts on this issue that is obviously of extreme importance to all of us.

I'd also like to take a moment and especially thank three people who really did all of the hard work for getting this particular meeting set up. Those people are Tywanna Paul from the FDA Kansas City district office, who really, as far as I understand, did all the logistical work.

And Tywanna, could you stand up.

This is the person, if you have any questions about logistics or about what's happening here today, please feel free to ask her, because she's the one who has all the logistical answers.

Thank you very much, Tywanna. We appreciate it.

I'd also like to thank Bill Sedgwick, who's the deputy district director here in Kansas City, and all of his staff, whom you met outside, who were working so hard to get you checked in and try to meet your various needs while you're here.

I'd also like to thank Linda Grassie from the Center for Veterinary Medicine from Washington. She has been the person from CVM who's been working with our Kansas City colleagues to get this particular meeting organized and get all the logistical work done.

So all the praise for this particular meeting in this room and everything that went into it clearly goes to those three individuals. And a special thank you to all of you.

For those ever you who might

not have ever been to or taken part in what we call a Part 15 hearing, let me take just a couple of minutes to try to review for you what the purpose of this meeting is and how these hearings are conducted.

These are general public hearings that the FDA conducts under our regulations. They are simply to provide a forum that, when there are issues that are of extreme importance to the FDA, when we are beginning to look at how we do certain things in our business, when we're beginning to look at our rules and regulations, when people are raising issues about the adequacy of rules, regulations, procedures, it gives us an opportunity to put that information out and to tell the public that these are the kinds of things we're hearing, these are the kinds of things that we have questions about and concerns about, and, before we get into any kind of formal rule-making, to hear from the public what they think about these issues and where they think we need to go -- or perhaps don't need to go -- on a given issue. And that's really what the purpose of this meeting here today is.

As we said in the Federal Register that went out announcing this meeting, there were a whole host of issues relative to our present feed-back rule that we have some questions about. I think as all of you are aware, this particular rule was promulgated back in 1997. We've had a four-year, four-and-a-half-year experience with it now, and in that period of time much new has been learned about BSE and CJD and variant CJD.

We've seen BSE spread now into continental Europe, we've seen it spread into Japan, and because of these things I think we felt like it was an appropriate time to look back and to ask ourselves whether our present feed rule is, indeed, adequate. The answer could be yes. It could be that it's perfectly adequate, that it does what it's intended to do, and that no changes in it are needed. It could be that, indeed, it needs to be tweaked, that there are things that we've learned, there are things that we haven't done as well as a larger community as we thought we could when that rule was promulgated, and so we need to know that.

As all of you know, the process

for looking at that rule begins with this Part 15 hearing. We'll get a lot of different viewpoints today, and that's okay. That's the purpose of this.

If the decision is that, indeed, perhaps some changes in the rule are necessary, we would go forward with a proposed -- with what's called a Notice of Proposed Rule-Making where any changes in the rule would be specifically outlined and any new wording for a revised rule would be printed for public comment. After that public comment came in, then the process is such that we would go forward with issuing a final rule that would, indeed, promulgate any changes, if, indeed, any changes were needed as we go along.

So this is not the end of a process today; this is clearly just the beginning of a longer process if, as I said, the consensus or the idea at the end of the day is that our present rule needs to be tweaked to meet the new knowledge and the new contingencies that we have.

In a Part 15 hearing, as I said, the purpose of a Part 15 hearing is for us

up here on the panel, representing different parts of the federal government, to listen to what you all have to say. This is not a forum for us to announce new policies, to say this is where we think we're going or where we don't think we're going. This is really a chance for you to tell us what you think we need to be doing relative to the issues that are germane to the topic today.

One of the rules of Part 15 hearings is that when your colleagues get up to speak, you cannot cross-examine them. This not a time to have he said/she said/they said and have it go back and forth in the audience. And I think in the many Part 15 hearings that I've been part of, people have been very respectful of that. They've noted that there are people who have different opinions. And, indeed, this is one of the glories of our system, that we have an opportunity to come forward and give those opinions, knowing that everyone who gives their opinion will be shown the respect they deserve. And I will assure you that will be the way this particular hearing is conducted.

After a person speaks and gives

his or her opinion, people in the panel here are free to ask clarifying questions to follow up, that kind of thing. But I am going to try to do the best I can to keep us on time. As you can tell from the agenda, we have a fairly full agenda. People have been limited to a maximum of fifteen minutes. As you get close to that fifteen minutes, I will -- we don't have any red lights or anything like that, but once your fifteen minutes is up, I will interrupt people and ask them at that time to start to bring their presentation to a close.

I hope all of you will be respectful of each other. I hate for us to go over early in the morning such that people who are scheduled later in the afternoon feel rushed or feel like they're not going to have the time that they deserve to have.

By law one of the things that we have to do with these hearings is to provide at least an hour where people who have not registered to talk have the opportunity to talk. In the Federal Register we announced that that hour would be the hour between 4:00 and 5:00. So we will be in session at least until 4:00 in

case someone read that the public session for people who were not registered begins at 4:00 and shows up at that time. If, indeed, we have no one at 4:00 who wishes to speak as an unregistered speaker, then I will close the session at that point in time. But we will be in session until 4:00 to meet that contingency of our procedure here.

Having said that, let me take a few minutes here and just introduce my fellow panel members. I think most of you probably know these individuals, but for those of you who don't, starting on my far right here is Dr. Kathleen Akin. She is from the USDA from the APHIS part of USDA. She is a member of the TSE working group at USDA. And she is the area veterinarian in charge at the Lincoln, Nebraska, post of USDA. And she will be the APHIS representative on the panel today.

The lady sitting directly to my right is Dr. Delia Parham. She's from the Office of Public Health and Science at the Food Safety Inspection Service in Washington, D.C. So she'll be the FSIS representative here today.

And these are my two USDA

colleagues who are part of this federal government panel. The gentleman sitting to my left -- to my far left is Dr. Steve Solomon. He is the deputy director of FDA's Office of Regional Operations in Rockville, Maryland.

And to my immediate left is Dr. Steve Sundlof, who is the director for FDA Center for Veterinary Medicine. So Dr. Solomon, Dr. Sundlof and I are the HHS/FDA representatives to this panel.

There is also a group of individuals who are in the audience with whom we at FDA meet on a quarterly basis. These are representatives from AAFCO, the American Association of Feed Control Officials, and also NASDA, the National Association of State Departments of Agriculture. And we'll be meeting with them tomorrow morning in a closed session, a session between state and federal government officials. And they are here with us today to listen and also to hear what you have to say, because, as you know, they play a crucial role in this particular regulation and enforcement of this regulation.

And so I'm going to introduce

the ones that I know who are supposed to be here. If they're here, I'd like to ask them to stand when I call their names so you know who they are, and you can speak to them if you wish.

First is Fred Daley, who's the director of the Ohio Department of Agriculture in the far back.

Second is Benjamin Jones, Ben Jones, who's with the Texas Feed and Fertilizer Control Services. Ben is over here.

Ali Kashani from the State of Washington Department of Agriculture. Ali -- there's Ali over there.

Steve Martin from the Michigan Department of Agriculture. Steve is up here.

Eric Nelson from the Wisconsin Department of Agriculture, right there.

James Watson, who is the State Veterinarian with the Mississippi Department of Agriculture and Commerce.

And finally Steven Wong from the California Department of Food and Agriculture.

Thank you all.

And we also have one

international member of our group, Linda Morrison, from the Canadian Feed Inspection Agency. And Linda's back there.

So if you all have issues or concerns you would like to express to them relative to their national or state responsibilities, by all means do that.

Are there any logistical questions or anything that people have about how we're going to proceed today before we get started?

(No response.)

DR. LUMPKIN: Okay. According to my watch -- which I did set on Central time this morning -- it is 9:15, and according to our agenda we should be ready for our first spokesperson.

So I'd like to call Dr. Michael Hansen, who is a research associate for Consumer's Union. And let me say to Dr. Hansen coming forward, if I misrepresent your title or mispronounce your name, I apologize. At this point, please do correct it for the record.

As all of you know, on these hearings we do make a verbatim transcript. Our

transcriptionist, the court reporter, is up here. Please do speak up and only speak into a microphone so that she can indeed hear what you have to say.

Thanks very much. And I turn the floor over now to Dr. Hansen.

Thank you for being with us.

DR. HANSEN: Thank you very much. I'm glad to be here, and I actually would like to -- Consumers Union would like to thank the FDA for holding this hearing. I also would like to say that we are going to submit written comments to the docket, so I don't have any prepared testimony that I will hand out.

But we do think that the FDA needs to dramatically -- well, needs to change the rule and to actually expand it.

I am going to go through a little bit of some of the old science and new science which raises concerns for us, and then try to go through a number of these questions and give our responses to them.

For some of the old science that I think we have to look at, in our mind, the rule is too restrictive by just dealing with

BSE and new variant CJD. We, in fact, think that the agencies here should be concerned with pretty much all forms of TSEs and other forms of CJD besides the new variant. All forms of CJD there should be concern over.

And here's some of the science behind why we have those concerns.

First for some of the old science, there's something called the Gibbs Hypothesis after Clarence Gibbs at NIH. And he pointed out that probably the TSE that we understand the best is Creutzfeldt-Jakob disease in humans. It's been studies for quite a while, and we know that it occurs supposedly at the rate of one death per million population per year. Now, it's been pointed out in the United States that about fifteen percent of all the cases of Creutzfeldt-Jakob disease are so-called familial cases. And what those are is those are people that have quaint mutations in the prion gene. And as we all know, the prion protein that which is thought responsible for this disease -- that is, the mouth form version of that prion protein -- the normal version is found on the surface of all nerve and many

lymphocyte cells within all mammals. So we know that in humans if you have a point mutation at a given amino acid on that prion protein, it somehow changes it to make it appear to spontaneously flip over, so that people with those mutant genotypes, they spontaneously come down with CJD and they pass it on to their offspring as though it were a dominant trait.

So since that happens with humans, there's no reason to suspect -- since all mammals and all animals have these prion proteins, there's no reason to suspect that similar mutations can't also happen at random. That's why Dr. Gibbs always said that he actually expected that at a very low rate, one in a million, one in two million, one in three million, they would expect to see TSEs in virtually all mammals. And he thought that the reason that that wasn't -- that we don't have evidence of that is because who would notice a slightly ataxic wild animal once it has subtle symptoms?

So I think there's -- because of the fact that you can have mutations in the prion gene that we know lead to disease,

regardless of any kind of outside input in terms of what the organisms, what the humans, are eating, that that suggests that the same thing could happen in other mammals. We should be concerned, for example, in cattle in the U.S., not just about BSE coming from Britain, but there might be a TSE already existing in cattle in this country.

In fact if you look, there is indirect evidence of a native TSE in cattle in the U.S. And the evidence comes from two sources: One from the transmissible meat encephalopathy outbreaks. That's TSE that occurs in meat. There's been a number of outbreaks in the United States. The first one which really raised concern of scientists was in -- well, two of them. In 1961, there was an outbreak on five farms in Wisconsin. They were able to -- and they were in adjoining counties. All the farms with affected animals used a ready-mix feed ration which came from the same feed plant, so the scientists assumed that the feed source was the source of this infection agent, but there was many things in this ready-mixed feed, so they couldn't tell.

Two years later, in 1963, there were two more cases of TME outbreaks on mink ranges in Wisconsin. This occurred on two farms that were about two counties apart. And when they went and looked, they found the one surprising thing was that, quote, "Beef carcasses unfit for human consumption" or so-called downer cows, that came from Farm A were fed to minks both on Farm A and Farm B. As the scientists noted -- this is Dr. Gary Hartzog, Diedra Berger, they said, quote, "Since mink on both farms developed the disease almost simultaneously, we believe this feed component has to be incriminated." In fact, the following year, in 1964, at the NIH-sponsored meetings on TSEs and scrapie, Drs. Berger and Hartzog were there hypothesizing that there were sporadic cases of a bovine TSE occurring in the U.S. under the clinical picture of downer cows.

We flash forward to the next case that happened in Stetsonville, Wisconsin 22 years later, in 1985. Dr. Richard Marsh investigated those cases. In that case, 95 percent of the diet was downer cows. He did a lot of experiments in the lab and was able to

show that you could take brains from these animals and just feed them to mink, the mink would come down with the disease. For the people that thought that TME was coming from scrapie, he tried to get scans on every scrapie strain he could find, and he could never transmit it orally to mink. But they were successful with this cattle.

So there was the evidence from TME, and then also there's been evidence from the scrapie-infested cattle studies. The first one that took place in Mission, Texas, where they injected scrapie into ten cattle in the '70s, what happened is two to four years later three of the animals died, but they didn't show -- there wasn't classic spongiform damage in the brain. So at the time, some of the scientists said, "No, we don't think this is TSE."

Ten years later, in the late '80s, when they finally had the antibodies, they were able to go in, check the brain cells of ten animals, and, sure enough, the three that died, they tested positive. And actually Gibbs was able to take brain material from those animals

and transmit them to mice in the lab, showing that they indeed were TSE. The clinical symptoms were very different than TSE in Britain, and, in fact, since then, there have been further passages of mink from Stetsonville. There have also been passages from Caterburg, Wisconsin, and from North -- Dakota Springs have all been successful. So therefore that suggests that there might be a TSE that's occurring in the U.S.

Now, if you look at some of the new science that is out there, that is pretty frightening. In the last four years, NIH, the lab in Montana, has been able to show with studies with scrapie that was done in hamsters, they found that some animals could be silent carriers. They could appear perfectly healthy; that is, you put scrapie into hamsters, they get diseased. You inject the mice with hamster scrapie, they live perfectly normal lives. They are fine. When those mice die, you inject them into other mice, nothing happens; but if you inject them back into hamsters, the hamsters come down with hamster scrapie with a longer incubation period, which suggests that now you

can have silent carriers. So that means you can have this indirectly; that is, if you feed potentially contaminated, say, meat from a cow that has a TSE, you can legally feed it to pigs, grind up the pigs and feed the pigs back to the cattle. So there's an indirect loop there that raised a lot of concern at the time when these studies came out, particularly in Europe. Also some new studies that were also done in Hamilton. DCN Petro conversion studies have been able to demonstrate that BSE does convert to human prion protein in the lab, and furthermore it converts to prion protein -- that's methionated code on 129 -- three times more efficiently than it is failing at 129. We know that that fits with what we see because met-met -- if you have -- if you're a met-met homozygote at code on 129 prion protein for humans, you're over-representing -- you have a higher chance of getting so-called sporadic CJD, while recent studies have also demonstrated chronic wasting disease which occurs -- also converts to prion, and it does it at about the same rate that BSE does.

Finally, they were able to show

that scrapie did some converting at its human prion proteins. Now, people would say scrapie has been around for hundreds of years. There's no evidence that it can cause any problems. However, just last year, 2000, Corrine Lasniecess's (phonetics) lab in France, doing some strain type work, which is considered the gold standard -- and that's where you take the TSE posivan and inject it into the brain, certain genotypes of mice and then you look at eight different areas of the brain and do a score for the damage -- they were able to show with the strain typing that they've been able to differentiate many strains of scrapie, and, in fact, this was what the final link that convinced people that new variant CJD was BSE in humans, because when you do the strain typing, the new variant CJD caused one signature, so-called sporadic CJD caused another one; but new variant CJD looked exactly like BSE. When they passed the BSE into mice, into felines or wild ungulus in zoos, the strains all looked identical.

So what the French did was they had a bunch of growth hormone cases. They

decided to use some strain typing and try to figure out maybe where some of those growth hormone cases came from. And what shocked them is one of the French cases, when they strain-typed it, it didn't look at all like variant CJD, but to their amazement, it looked exactly like a French scrapie strain.

Now, they looked at a French scrapie strain, sporadic CJD and variant CJD, and what amazed them is now the strain-typing evidence from this one athogenic case where it strain-types out to a French scrapie strain -- not a U.S. scrapie strain, but a French strain. This was a French person that died of CJD from growth hormone injections. So that does suggest that strain-typing, that, in fact, that came originally from sheep. And I know scientists in Europe are very concerned about this.

There's also been four case-controlled epidemiology studies which have linked sporadic CJD to the consumption of brains and other materials.

So because of this, we think the present rule should be expanded; that is, the additional objectives should be that we want

to minimize GSEs and new variant CJD. So we think that the present day ban on mammalian proteins in ruminant feed should be broadened and the new parameters should be that all mammalian proteins should be considered -- should be banned, and none of those should be permitted to be in the food fed to food animals. So that is all mammalian proteins, with no exceptions, and you broaden it to not just ruminant feeds, but all food animals. That includes fish and fowl now, of course, this fowl protein and fish protein to be able to feed the animals.

And as for the exemptions, I'll go through those now. Therefore, we think this exemption of pure porcine and equine protein in your definition of "mammal," that should be revoked; that is, you should not be able to feed the porcine, because the way it stands now, again, there's an indirect route. You can feed material from the cattle to pigs, grind up the pigs and feed it back to the cows. So we think the porcine and pure equine portion should be revoked. The milk and dairy products, we think, is fine. The blood and blood-clotted exemption

needs to be revoked because there is a -- we know that the TSE agent can be found in the blood, and we also know that there is increasing use of blood plasma and blood clot instances, that weaning calves, that we don't think that's a good idea. And finally the gelatin should be revoked as well.

Now, there's also another provision in that Section 589.2000 that we are concerned with, and that was this provision that says if you had a foolproof test for testing for the presence of TSE -- one doesn't exist yet, but if you have it, if something tested negative, then you would be exempt from their requirements. But if something tested positive, what we do with something that tests positive, and under the present regulation, something that tests positive can go into the animal feed supply, it just needs to be labeled "Do not feed to cattle or other ruminants." We think that that is crazy, and that any TSE-positive animal should not be permitted into any food chain, human or animal. We point out that that was the first recommendation from the WHO expert consultation that was held in 1996 on public

health impacts.

DR. LUMPKIN: Dr. Hansen, can I ask you to wrap your comments up? Your fifteen minutes are up.

DR. HANSEN: Yes. Very quickly, we do think the -- because of problems with cross-contamination that the FDA should require dedicated facilities for the production of animal feeds. They should require dedicated transport.

And then finally, one more thing. For the recordkeeping requirements, they presently stand at one year. That's inadequate. We believe it needs to be ten years, because the average incubation period, for example, for BSE is five years. So you need to keep these records so that if something happens you'll be able to potentially trace the feed back to the source. And given that BSE has an incubation period between three and eight years, that there are some forms of scrapie that are even longer, we think we should account for ten years.

Finally, for the label requirements, we agree with the FDA that we think that the label should be simplified and

say, "Not to be fed to cattle or other ruminants," that that should all be spelled out.

And again, we'll do very detailed comments to the entire group.

Thank you.

DR. LUMPKIN: Thank you very much.

The next person who is scheduled to speak is Mr. David Miller, the director of the commodity services at the Iowa Farm Bureau Federation.

As he is coming forward, as we pointed out, people are encouraged to submit written comments. The docket will remain open for the reception of the comments until November 21st if you wish to get them into the docket.

Also, if you happen to have either a written or electronic copy of your presentation, Linda Grassie, who is sitting at the end of the first table here, is collecting those to have them put into the docket.

Thank you very much.

Mr. Miller, please.

MR. MILLER: Thank you.

The Iowa Farm Bureau Federation

appreciates the opportunity to provide oral comments to the Food and Drug Administration in regards to the rules governing animal feed and regulations and the issues that FDA has raised in the Federal Register.

Iowa Farm Bureau believes that the current rule is generally sufficient to provide necessary public health protection. We believe that farmers and ranchers are taking the appropriate steps to comply with the ruminant feeding ban. As with any new rule that radically changes production practices and requires significant alterations in recordkeeping and other management practices, complete compliance was not instantaneous with its implementation. We believe that compliance with the ruminant feeding ban is at a high level and increasing. However, it would be appropriate for FDA, in cooperation with state inspection programs, to maintain surveillance of compliance through spot checks and records review of regulated firms.

The ruminant feed ban rule was part of a three-pronged approach to reduction of risk as it pertains to introduction and spread

of BSE in the United States food supply. We believe that the rule is adequate to meet its objectives. Government studies have indicated that the risk for introduction and/or spread of BSE through cattle feed is near zero, especially if we can achieve complete compliance. The FDA arguments that were put forth at the time of the adoption of the 1997 final rule were compelling. Those arguments were based on sound science and a review of industry practices. The basic risk factors that the final rule aims to reduce are essentially the same as in 1997, thus the regulations that were deemed to be based on sound knowledge and scientific fact should continue to provide the level of risk reduction being sought.

To date, we are not aware of any scientific basis for broadening the ban on the use of specified mammalian proteins in ruminant feeds. In the preamble to the 1997 rule, FDA provided scientific justification for the exemptions offered in the rule. We believe those exemptions are still scientifically justified. The safety of blood products has been reconfirmed by scientific tests. We

recommend that FDA continue to monitor the science and consider changes when there is compelling scientific justification and evidence.

We do believe that the feeding of poultry litter and other recycled poultry waste to cattle could present a means for the spread of BSE, if the disease were ever found in the United States. We recommend that FDA and other appropriate agencies conduct the necessary research to quantify the actual risks associated with feeding of poultry litter and other poultry wastes to cattle. If the risks are as minimal as they appear to be, then no additional action should be taken. If the risks are determined to be significant, then the Iowa Farm Bureau would consider supporting a modification to the prohibited materials list to include poultry litter and other poultry wastes.

We believe that "road kill" and all ruminant wildlife should be eliminated from all rendering. Such animals should be buried or incinerated, but should not be allowed to enter the feed supply chain. Domesticated deer, elk and other such animals should be treated as any

other livestock species.

Imports of feed and animal protein products should be restricted from those countries with BSE or which are not actively performing surveillance in accordance with the Office of International Epizootics. We support the regionalization of certain areas like the European Union because of the free flow of goods within and among member countries. We are concerned, however, that insufficient attention is being paid to transshipment of animal products from restricted countries or areas through third-party countries. We are also concerned that such products may be mislabeled when being transshipped. We urge the FDA to strengthen the port inspection program and to increase its surveillance of transshipments.

We believe that imported feed products pose the greatest threat of introduction of BSE into the United States. We urge FDA to increase its efforts in this area, giving it more attention and funding.

We believe FDA should consider making some modifications in labeling requirements. It is becoming standard industry

practice for producers to be required to certify to those purchasing their cattle that they have not been fed proteins derived from either ruminant or mammalian sources. Many producers have indicated that this is difficult if the label does not at least distinguish whether the protein in the feed is derived from ruminant or non-ruminant sources. Currently producers do not have sufficient information to really make this certification. Feeds containing animal proteins often only indicate that the feed contains animal proteins. The producer must assume what type of animal protein from the presence or lack of a warning statement. We believe this is insufficient. Producers should have the necessary information to make the certifications that the marketplace is requiring.

Producers in Iowa are concerned that the lack of specific information with respect to the type of mammalian protein sources could lead to producers making inaccurate certifications. We believe broader classifications of protein sources such as "non-ruminant-derived animal proteins" and

ruminant derived animal proteins" may be sufficient, rather than species-specific classifications. We do not believe it is necessary for the label to list specific species that a feed should be fed to. The current label warning is understood by producers.

Previously, FDA has indicated that the cautionary statement serves no useful purpose on pet food and feed for non-ruminant laboratory animals and cited this as one of the bases for the current exclusion. Iowa Farm Bureau is unaware of any changes in industry practices or risks to food safety that have been introduced because of this exclusion. We see no need to remove the exemption and believe that FDA's justifications of this labeling exemption remain valid.

We believe that the imposition of a requirement that dedicated facilities be used for the production of animal feed containing mammalian protein would provide little, if any, reduction in risk, given the extremely small number of commingling incidents and the very low level of commingling.

Similarly, we believe that

the feed industry to implement a licensing program would not be a wise use of agency funds.

We believe the federal commitment to a full and ongoing inspection program is vital to the success of the ruminant feed ban as a risk mitigation tool in the fight to keep the United States free of BSE. We believe that we must have 100 percent compliance and 100 percent inspections. This will require state and federal agency cooperation as well as industry action. We urge FDA to do a review of the third-party certification programs that have been developed by the industry. If, upon review, these third-party certification programs are deemed reliable and responsible, then we would urge FDA to officially recognize and cooperate with such programs.

In summary, we believe the current rule governing the use of animal proteins in ruminant feeds is, in general, working well. Areas that might be considered for modification to further reduce any potential risks are restrictions on feeding of poultry litter to ruminants and more extensive monitoring of imported ruminant feeds. We urge

strong enforcement of current regulations, but do not believe that additional regulations are necessary to increase compliance. We believe a federal commitment to a full and ongoing inspection program supplemented with industry certification programs are essential elements of this effort to reduce the potential for introduction of BSE and minimize the potential for spread of the disease vector should it ever occur in the United States.

We appreciate the opportunity to provide these comments regarding the prohibition of specified proteins from ruminant feeds.

DR. LUMPKIN: Thank you, Mr. Miller, for joining us.

Are there any questions of the panel for Mr. Miller?

(No response.)

DR. LUMPKIN: And I didn't ask the panel: Any questions of Dr. Hansen? I forgot about that.

(No response.)

DR. LUMPKIN: Okay. Fine.

The next speaker is Dr. J.P.

Fontenot, who is the John W. Hancock, Jr. professor of animal science at Virginia Polytechnic Institute and State University.

Dr. Fontenot.

DR. FONTENOT: Thank you very much, sir. And I appreciate the opportunity to appear here to talk about the feeding of poultry litter. The main reason I requested to appear is that I had heard that there had been some objections raised in terms of feeding poultry litter in relation to BSE.

I'll have to crank up the machine here. Just a minute. It takes a little while.

This is what we're talking about. In other words, here's where the poultry litter is produced. We have many of those throughout the U.S., especially in poultry-producing states.

I'll give an outline of the presentation. I'll talk a little bit about the history of the poultry industry, the class of cattle that are fed poultry litter, quality of animal products, safety of feeding poultry litter, and also look at regulations and

practical feeding.

These are the amounts of waste that are produced per year. You'll notice that somewhat over five million tons of poultry litter are produced per year. In terms of feeding poultry litter, it is fed mainly to beef cows and stocker cattle. Little, if any, is fed to fattening cattle. Substantial amounts are fed in broiler producing states. In Virginia it is estimated that 20 to 25 percent of the litter that is produced is fed, which would amount to somewhat over 100,000 tons. In the U.S. about 5.6 million tons of broiler litter are produced. It would amount to -- if we say twenty percent is fed, that would amount to about one billion tons per year. So it is a substantial amount.

Description of the poultry litter. Poultry litter is an accumulation of excreta, some wasted feed, feathers and bedding material. Bedding material is usually wood shavings, sawdust, peanut hulls or other fibrous materials.

Options for utilizing animal wastes. It's been applied to the soil for centuries. It can be used also as a substrate

for methane generation from microbial and insect protein hydrant. The most economically feasible is one of feeding farm animals.

Nutritional value of poultry litter. It is quite nutritious. It has 25 to 30 percent protein on a dry matter basis, fifty-five to sixty percent TDN. It is rich in minerals. If you want to compare it to, say, feeds -- feedstuffs, it would be at least equivalent to good quality alfalfa hay or higher; in other words, it's higher in protein, it's higher in energy and it's higher in some of the minerals, and the performance of animals fed poultry litter has been equal to animals fed traditional feeds if the nutrients were equalized.

About the quality of animal products from animals fed poultry litter. There has been very extensive research. There have been no differences, no deleterious effects on the carcass quality. Furthermore, in cooking and taste tests with animals fed poultry litter, there has been no harmful affect on feeding the litter on the taste of the meat.

Let's look at the safety, then,

of feeding poultry litter, which is one of the things that we need to be concerned with. This young lady here is cooking steaks for her family, wants to make sure that it is safe.

The history of the poultry litter feeding -- this is a little bit out of order. Poultry litter has been fed to beef cattle for at least 40 years. The research on feeding poultry litter started in the 1950s. We started doing our work in 1963.

In residues -- this is the slide I was getting to -- there have been no accumulation of pesticide residues after a one-day withdrawal, we found that there was no accumulation of heavy metals, and after a five-day withdrawal, although there were medicinal drugs in the litter, there were no medicinal drugs found in the meat or the litter. So the meat has been found to be safe.

In terms of were pathogenic organisms, there are potential pathogens. The litter should be processed; however, there is no information concerning BSE on poultry litter.

Processes that are effective to process poultry litter: Dehydration, ensiling

and deep-stacking. I think you are all familiar with ensiling and dehydration. Deep-stacking would look something like on the next slide.

This is a large structure, and many of those in the poultry-producing units such as Virginia, where we have deep-stacking of litter, it's stacked several feet high. It undergoes the heat and does destroy the pathogens.

Although poultry litter is a potential source of pathogens, in a recent Georgia report, they found no salmonella. E.coli was isolated from 86 samples. Some of that had been processed and had not been processed. However the litter should be processed to destroy any potential pathogens.

Clostridia problem, I would like to address. In some countries there have been outbreaks of botulism occurring in cattle fed poultry litter. In all cases this was due from Clostridium botulinum arising from poultry carcasses in the litter. There have been no cases reported in the U.S. I have followed the cases very carefully in all other countries -- I'm not going to name them -- but there's none

in the U.S. However, it is important to remove the carcasses from the poultry house.

In terms of animal health in the U.S., we have observed copper toxicity in sheep and poultry litter. This is not a serious problem in cases of cattle because they are not nearly as sensitive as sheep to copper. As a matter of fact, over a seventy-year period we fed high-copper poultry litter to beef females every winter for seven years, and we observed no symptoms of copper toxicity. The liver copper levels were up in the spring, but then after they went to pasture the next fall, they were back down.

Okay. In terms of regulation, most states follow the Association of Feed Control Officials in terms of their model regulation, which means the waste must be free of pathogens. If the waste does not contain drug residues, no withdrawal period is required and can be fed to any class of animal. If the waste does contain objectionable residue, a fifteen-day withdrawal is required.

Feeding poultry litter and BSE. This question was addressed by FDA in 1998. The

code is given here. The question that was raised was: Can chicken litter be fed to cattle if poultry might have been fed prohibited material? And the FDA's answer is yes. The FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract.

FDA expects the states to require recycled animal waste to conform to the definitions promulgated by AAFCO's publication, which is described in the model regulation.

Practical feeding. As I said earlier it is fed primarily to beef cows and stocker cattle and is usually mixed with corn or other palatable materials. Small amounts of hay or straw is usually fed.

The value of poultry litter, about a hundred dollars a ton, based on its nutritional value as a replacement for hay. And many times it is. It's worth about sixty to eighty dollars per ton. Soil application, it's worth about $25 per ton, about four times as much as a feed than a soil application.

Okay. One of the advantages in the feeding of poultry litter to beef cattle. For the meat producer it's an economical feed

and it's an alternative feed for such things as during a drought. In some parts of the southeast we are running into a serious drought, and a lot of poultry litter is being fed as a substitute for hay, because hay is becoming short. From the poultry producer, it provides excess soil application. From an environmental standpoint, if we can transport litter further from the production areas because of its value and also keep the high level of nitrogen phosphorous from going to the water supply due to high excess levels of soil application.

In summary, then, we feel that poultry litter can be used as a feed stuff if processed properly. It is a safe feed. Performance of cattle fed the waste is similar to that of cattle fed traditional feeds. With good management and appropriate withdrawal, the litter does not result in harmful residues in animal tissue. The higher value of litter as a feed than fertilizer would justify transportation of the waste outside of the areas where it's produced.

We feel there is no reason to change the regulation, and we feel that FDA

should stay with its original statements published in 1998.

Again, thank you very much for the opportunity to appear in this hearing.

DR. LUMPKIN: Thank you Professor Fontenot.

Are there any questions of the panel?

I have one, just since we've got a little bit of time. You mentioned the composition of what we generically call poultry litter. One of the things is spilled feed. Do you have any idea quantitatively how much of poultry litter consists of spilled feed?

DR. FONTENOT: I have no data at all on that. But my impression is that with the controlled conditions used, you know, by the poultry industry today, we still do that -- we still say that. But the fact of the matter is that when we made this statement, this was more like thirty or forty years ago. I think with the modern technology, it's -- although I have no measurements at all, I think it's very minimal.

DR. LUMPKIN: Thank you, sir.

Thanks very much. We appreciate it.

The next person on our schedule to speak is James Hodges. He is president of the American Meat Institute and the AMI Foundation in Arlington, Virginia.

MR. HODGES: Thank you, Dr. Lumpkin.

Today I am representing the American Meat Institute. We are the nation's oldest and largest meat packing and processing industry association. Our members slaughter and process over ninety percent of the nation's beef, pork, lamb, veal and turkey products, and we produce more than sixty percent of the rendered by-products that are manufactured for animal feed in the United States.

We appreciate the opportunity to comment on the FDA animal feeding regulations that were put in place to help prevent the establishment and amplification of BSE in the U.S. cattle herd.

AMI has and continues to support the scientifically based regulations that restrict the use of animal protein derived from mammalian tissues for use in ruminant feed.

A careful analysis of the facts suggests no regulatory changes are warranted at this time.

I have three messages to leave with you today:

First, we do not have BSE in this country; second, we have taken prudent steps to prevent BSE from entering country; and, third, if BSE were to find its way into this country, we can diagnose it, isolate it, and prevent it from reaching consumers in a swift and decisive way. Our risk of BSE from domestic cattle is not zero, nor can it ever be. But our risk today is the lowest it has ever been since the disease was first recognized as a threat to the U.S. cattle population. Any changes contemplated in the regulations must take that into account.

Let me focus for a moment on my first message. We do not have BSE in this country. That fact bears repeating because it tends to get lost in the emotional reactions that often surround a public debate on ways to reduce the risk from BSE. Hysterical and speculating news reporting that often accompanies that debate further obscures the

successful track record that we have established.

The BSE crisis in Europe, and now Japan, has provided strong incentives for the U.S. government and the U.S. beef industry to take aggressive actions to prevent this devastating disease. In fact, we took action so early that some people now seem to question why we aren't announcing new major efforts today. The answer? We took swift, science-based actions early on that have protected our livestock and given us the coveted distinction of being a BSE-free nation.

The purpose of this hearing is to solicit information and views on FDA's animal feeding regulation. But that cannot be done in isolation. It is important to remember that BSE prevention in the U.S. involves multiple programs that can best be described as a triple firewall strategy. This includes: One, a ban on the importation of cattle and beef products from countries with BSE; two, a statistically sound and comprehensive animal surveillance program to continually monitor for the presence of the disease; and, three, ruminant feeding

restrictions to prevent the amplification and spread of the infective agent in the unlikely event BSE occurs in our domestic cattle.

Taken together, these efforts provide the best reasonable assurance that U.S. cattle will remain BSE-free, and that U.S. consumers will not be exposed to any related health risk. That is not to say we should rest on our laurels. We must continually evaluate and improve our preventative control measures if warranted, and we must assure our regulatory agencies are provided with the necessary resources to do their job.

AMI believes the present FDA animal feeding regulations are appropriate, given the low level of risk that BSE will occur in this country. Our goal is not to change the regulation but to achieve 100 percent compliance with the existing regulation. AMI's worked with several trade associations to supplement FDA's compliance activities by establishing a program to certify that animals sold for slaughter have not been fed any feed containing protein derived from mammalian tissues that is prohibited by FDA regulations. The program was implemented

earlier this year, and our internal surveys indicate that a vast majority of the animals that come to slaughter are marketed under these types of certification programs. A copy of the program details will be provided for the public record.

Finally, it is important to remember that BSE has been diagnosed only in Europe and Japan. More than 99 percent of the diagnosed BSE cases have occurred in Great Britain, where the incidence rate has dropped dramatically after animal feeding restrictions were implemented.

The U.S. has very different risk factors. Our livestock populations are very different, as are our rendering, feeding and production practices. In addition, these countries are in the midst of a crisis, and crises warranted strong and dramatic actions. In contrast, we do not have a BSE crisis in the U.S. It is critical that our BSE prevention policies reflect that fact and that our policies are supported by the best available science.

Again, I appreciate the opportunity to present the views of the American

Meat Institute.

I'll be happy to answer any questions the panel may have, and I will leave copies of my prepared testimony for anyone in the audience as well as for the public record.

DR. LUMPKIN: Thank you, Mr. Hodges.

Any questions from the panel?

DR. SUNDLOF: Jim, you mentioned that the significant percentage of the cattle going to slaughter now are covered by the certification programs. Do you have any kind of statistics on that?

MR. HODGES: We don't have firm statistics, but if you just survey our major members, all of them are using -- all of them are using some type of certification program -- if nothing else, to meet customer needs. So I would stand by my statement that it's the vast majority rather than put a particular number on it at this point.

DR. LUMPKIN: Any other questions?

(No response.)

DR. LUMPKIN: Again, thank you

Mr. Hodges.

The next speaker is Michael Langenhorst. He's the past president of the National Renderers Association, Alexandria, Virginia.

MR. LANGENHORST: Thank you, Dr. Lumpkin. I'm also the president of the Adamex Group of Companies in Green Bay, Wisconsin. We are a renderer in Wisdonsin, so the first eight minutes of my clock or discussion will be on National Renderers Association and the last two minutes will be on behalf of myself and my company.

National Renderers Association is the international trade association for the industry that safely and efficiently recycles animal and poultry by-products into valuable ingredients for the livestock, pet food, chemical and cosmetic industries. The NRA represents 43 member companies operating more than 160 rendering plants.

We are very familiar with the issues we're discussing here today. Since the first case of BSE was reported in 1986 and through all the stages of the situation, we've

been proactive and have worked closely with the FDA and other government departments as well as affiliated industries to produce and promote safe feed. In fact, I believe that the support of the National Renderers Association and our TSE committee has been instrumental in the success of the surveillance program as well as the original rule itself.

There are seventeen questions we've been asked to respond to, but I would just like to comment publicly on a few of them. Written comments will be submitted by our industry before November 21st.

The main question is: What additional enforcement activities, if any, regarding the present rule are needed to provide adequate public health controls? Are there any suggestions for ways to improve compliance with the rule?

The NRA believes that the current rule provides adequate protection for public health and has accomplished its intended goals as laid out in 1997. We realize that there are big concerns expressed with certain aspects of the rule, but feel that these

concerns can be addressed by providing proper resources for inspections and data management.

There have been very few noncompliance events since the rule has been implemented. The majority of noncompliance issues come from incorrect inspection interpretation or incorrect data compilation. In fact, the recent APPI third-party certification program has shown a 98 percent compliance with the rule in the rendering industry. The other two percent have not been determined not compliant, but, rather, have not undergone third-party certification.

The NRA strongly supports and would participate in any effort to attain 100 percent compliance of our industry. We would not be opposed to licensing a rendering facility as it relates to compliance with the rule if this would help with enforcement so long as it does not become a bureaucratic nightmare. If anyone is not complying with the rule, appropriate action needs to be taken by the agency.

Much time and energy went into developing the final rule in 1997. It was felt

very strongly at that time that appropriate controls had been implemented to protect public health in the United States.

The rule is based on scientific risk assessment and was deemed to satisfy the risk at that time. It must also be remembered that the rule at that time was thought of as a firewall for the meat industry. We all know that the U.S. really has many firewalls in place relative to the BSE: The ban on imports since 1989, the surveillance program which exceeds OIE recommendations, mammalian feed ban of 1997 and now thirty-party certification.

We're at the lowest level of risk that we have ever been as a country. There's no need to reopen the rule, but rather we must strive for 100 percent inspection and compliance with the current rule.

The NRA strongly supports appropriate restrictions on the importation of feed and animal products. These restrictions should be based on a risk analysis and on a country's BSE incidence. The U.S. could accomplish this by establishing a category classification as practiced in other parts of

the world. The resulting import restrictions and policies would be based on the systemic classification category.

Coordination of programs and appropriate financial resources must be put in place to accomplish this initiative.

The NRA thanks you for this opportunity to address these issues. We are committed to protecting our public health and continue to be available to work with the FDA. As stated earlier, our common goal is to attain 100 percent compliance.

I would also like to present to the panel a third-party report that we have just had done for the rendering industry by the Sparks Company. And this is an economic impact for three scenarios.

Scenario 1 is a total animal protein ban -- feed ban to all ruminant animals. The total reduction in revenue to industry -- now, this is not a rendering issue, this is an animal agriculture issue. And I'm standing here as a renderer, but we all have to keep in mind that I'm not here trying to protect the rendering industry. What we're talking

about here is animal agriculture. The total affect of an animal protein feed ban in all ruminant animals is over $100 million a year.

Scenario 2 is a total ban on feeding of ruminant protein to all farm animals, including ruminant meat and bone meal to swine and poultry and ruminant blood meal and plasma to dairy, beef, swine and poultry. The total net reduction to animal agriculture of value would be about $636 million.

Scenario 3 is a total animal protein ban for all farmed animals.

There's a lot more involved with these things than just a dollar impact, but also the environmental impact. As much as 47 billion pounds of slaughter by-products could accumulate each year, or 64,000 tons each day. That means the rendering is going to continue. The product will probably be rendered and then still have to be dispossessed of. The effect on the economic impact of animal agriculture under that scenario is about 1.519 or 1.52 billion dollars year. So that will also be submitted as part of our report.

Let me change my hats very

quickly now and talk as a director of his own business and his own company to be concerned about. Even though I have been speaking on behalf of the rendering industry, it's not a rendering issue; it's an animal agriculture, public health and a common sense issue. But really it's an animal agriculture issue.

It must be remembered that meat and bone meal are the not the product of BSE, but rather was involved in the transmission of BSE. The feed ban in '97 eliminated that threat. Meat and bone meal is still a safe feed.

I'd just like to make the comment that animals are not ground up to affect other animals, as we heard earlier. Material is processed under time and temperature requirements and is considered that it is turned to protein meal, much like soybean meal. It could be safely fed to other food animals. It was safe before '97 and it is safe today. The only thing that's changed is that we're no longer feeding mammalian protein to ruminants. This was done as a precaution, not because meat and bone meal was considered a poison, a toxin

or a carcinogen, even though people treated it as a poison, a toxin or a carcinogen.

This needs to be kept in mind as the technology continues to improve. There needs to be attention paid to this in the future. Zero tolerance for a safe feed product is unwarranted. We've been taught to work from history, and the rendering industry has. We will not go down the slippery slope of the Europeans, trying to separate so-called good product from bad product. We are not Europe, but rather we're North America. We do not have BSE.

Thank you.

DR. LUMPKIN: Thank you, Mr. Langenhorst.

Are there questions?

(No response.)

DR. LUMPKIN: Thank you, sir.

The final speaker before our break this morning is Dr. Don Franco. He is president of the Animal Protein Producers Industry from Lakewood, Florida.

DR. FRANCO: Thank you, Mr. Chairman.

The Animal Protein Producers Industry is the association of the United States rendering industry that is responsible for biosecurity, and, as a result, the establishment of programs to ensure feed ingredient safety, including animal proteins that are used as ingredients in livestock, poultry, agriculture and pet foods.

In this capacity, the organization has followed the subject of bovine spongiform encephalopathy from the report of the initial outbreak in the United Kingdom in 1986. APPI is conscious of the complexity of the group of diseases collectively defined as the transmissible spongiform encephalopathies and fully recognizes the tentative nature of the science and the fact that BSE is the first disease in the annals of regulatory medicine, animal or human; that a rule was written with all the finite determination and affirmation of the cause of the disease. While this was unusual, APPI recognized at the time that the uncertainty of the circumstances mandated a necessity to establish a series of flexible controls that are in the best long-term

interests of animal and human health, and as a result, supported the agency in the quest to format a rule that would preclude any likelihood of the transmission or amplification of the infectious agent of BSE and ultimately the protection of the country's public health.

About 16 years after the initial report of BSE, we are still discussing the varied nuances of the diseases, including the current questions posed by the agency in their consideration of options, including aspects/concepts for modification, if applicable, of the existing rule.

While the complex issues and unanswered concerns of BSE mandate caution, the record clearly indicates that instituted controls in the United States started in 1986, immediately after the confirmatory diagnosis and continuing today in a constant manner by recently promulgated import restrictions are effective. Cumulatively, governmental policies are working and provide ample assurances that adequate constructive measures and controls are in place to ensure the safety of animal protein feed ingredients destined for

the feed food chain.

This assurance analogy is best exemplified by the final rule that became effective on June 5, 1997, and commonly referred to as the "animal feeding regulation." This comprehensive rule has addressed the potential hazard/risks associated with the disease and thus establish a visionary protocol to prevent the likely transmission and amplification of this infectious agent.

The rule was an excellent proactive response for public health protection at the time it was written. And in the absence of any changes in the risk factors of this country, remains so today. The regulatory agency developed a systematic method for education, inspection, for compliance, and enforcement, and collaborated with the states to assure success of the spirit and intent of the rule. APPI, therefore, as an organization, sees no need for any modification or reopening of the objectives or contents of the rule.

Retrospectively, the risk factors in the United States for a BSE incident are actually the lowest since the associated

links to the outbreak was first described in 1987-88 by epidemiologists in the United Kingdom. This has been affirmed in the peer review professional journals by APHIS, USDA officials, and in the Service's own brochures and publications.

The epidemiological case definition for the BSE outbreak in the United Kingdom has been clearly articulated by the following postulates. For an indigenous case of BSE to occur, a simultaneous -- and I say simultaneous -- presence of three factors is required: One, a large sheep population in relation to that of cattle, with a significant level of endemic scrapie; two, conditions of rendering that allow the survival of significant amounts of infectivity and; three, the use of substantial quantities of meat and bone meal from affected sheep or cattle in cattle feed.

The addition of a fourth factor applies to countries without the disease and has obvious relevance to the United States. Countries without BSE may also acquire it by the importation of live animals that could be incubating the infectious agent of the disease

or the importation of contaminated meat and bone meal that could be subsequently fed to susceptible cattle. Fortunately, our established rules in the last fifteen years have addressed the potential risk from a worst-case assessment and thus creating an impenetrable firewall to prevent, again, the likely transmission or amplification of the infectious agent, and, as a result, the protection of animal and human health in the United States.

APPI, then, is committed to the success and compliance with rules that advance the principles of our security, sustainable animal agriculture, food safety and the protection of human health. We pledge our resources to make this commitment a reality by working with FDA to achieving that objective.

We treasure the opportunity to be here and will provide further statements comprehensively in writing.

In closing, I reflect on historical debate that has been taking place in this country for the past 72 years. Although the disease differs dramatically from BSE, there were groups that have indicated since 1929 that

one day we are going to have a outbreak of foot-and-mouth disease in this country. Again, that is likely.

The message is that our regulatory agencies are apparently doing some things right. This applies to BSE. Not everything that should happen in life will happen. Applied to the science of disease transmission, unless the risk factors are present, cause and effect, Mr. Chairman, will not be realized.

I thank you.

DR. LUMPKIN: Thank you, Dr. Franco.

Are there any questions for Dr. Franco?

DR. SUNDLOF: Yes, have I one.

Don, you and, I think, two or three other speakers have said that the risk at this time is at an all time low for the introduction of BSE to this country. Can you list some of the factors that account for that? I mean, the rule is in place. We have import bans, we have our three firewalls. Are there other things based on the epidemiology of the

disease or other contributing factors that have led you to the conclusion that the risk is lower than it has been?

DR. FRANCO: Well, I did start off by looking at the complexity of the diseases, and I am very conscious of that. However, if you look at the things that first, by the industry, voluntary controls. In 1989, at Lonnie King's office, the rendering industry committed not to process sheep. And we went out and did just that, because that was the only available knowledge at the time. It was voluntary, and we did it. We then went out and we looked at other aspects of our security. We looked again at what was happening in Europe. We have been to Europe. We have been to Europe many times. We looked at research. But these diseases are, by nature, very, very complex. The answers don't come readily. So what we did, we looked at the rule, what you imposed on us. Some of the suggestions were hazard analysis, use of pathogen food safety. And I don't know what else we could do as an industry. I mean, we also looked at what was not done in Europe and did a comparative analysis of what we did.

And I think, again, without being repetitious or in any way redundant, that we have done what we need to do, both as an industry and as a government.

Thank you.

DR. LUMPKIN: Thank you again, Dr. Franco.

We have reached the time for our break. There is coffee and other things in the back. Please avail yourselves of it. And we will restart at a quarter till. So we'll restart the hearing at 10:45. Thank you.

(A recess was taken.)

DR. LUMPKIN: If I could ask you to take your seats, we'll get started here.

Before we get started with the next group of presenters, Dr. Sundlof asked to make a few comments, so I am going to turn the meeting over to Dr. Sundlof for a few minutes.

DR. SUNDLOF: Thank you, Mac.

I just wanted to say that the reason that I think we kept BSE out of this country is thanks to a lot of the folks in this room who have been very active and supportive of the feed rule and trying to do the best job that

you possibly can in making sure that it has been enforced and that folks are complying with it.

So I know you don't get enough credit for the things you do, and I just wanted to pass that along, that we couldn't do this without the help of the states, without the help of the various agricultural industries who play a major role in this.

We will be releasing today a CVM update which contains the latest compliance figures for the feed rule, and they have improved from the report that we issued in July.

In July we had an overall compliance, when we considered all the industries, the renderers, the licensed feed mills and unlicensed feed mills and some miscellaneous others, like ruminant feeders and et cetera, we had an overall compliance rate of about -- well, about 22 percent of the firms were not in compliance. You see the update that will show that about thirteen percent of the firms are not in compliance. So we're up to 87 percent compliance rate. Again, most of those are the unlicensed feed mills that seem to still have the highest rate of noncompliance. In

those firms that were found to be out of compliance on one inspection, on reinspection only six percent of them are continuing to remain out of compliance. So the numbers are going in the right direction. I think that's very good. As has been said a number of times this morning we still need to get that compliance rate up to a hundred percent. Looks like we're on the right trajectory.

DR. LUMPKIN: Thank you, Steve.

Our next speaker is Mr. Robert A. Frish, who is corporate counsel for Darling International, Incorporated, of Irving, Texas.

MR. FRISH: Good morning Mr. Chairman. I am Robert Frish, corporate counsel for Darling International, Incorporated, a rendering company with its corporate offices located in Irving, Texas. I'd like to thank you for opportunity to comment on behalf of Darling International on the status of the FDA's prohibition on the use of mammalian proteins in ruminant animal feeds. Please be advised that Darling International will be submitting written comments supplementing today's presentation that more thoroughly responds to the agency's notice.

Ensuring biosecurity and the safety of the food supply is an overriding concern for Darling International. Every year the American rendering industry provides a vital societal service in protecting animal and human health, effectively controlling or preventing the spread of diseases associated with animal tissues by removing and processing close to 50 billion pounds of animal and poultry by-products generated by the livestock, meat and poultry industries. As one of the largest independent rendering companies in the United States, Darling safely collects and processes more than seven percent of the total volume of these raw materials through its facilities located in 22 states.

In 1997, the FDA prohibited the use of mammalian tissues in ruminant animal feeds as a precautionary measure in order to prevent the transmission of TSE diseases to ruminant animals, such as BSE, despite the fact that BSE has never been detected and remains undetected in the United States. Even while acknowledging the abundant scientific uncertainty that existed as to the origin and

transmissibility of the disease, the FDA nonetheless adopted the rule as a measure to prevent, quote, "The establishment and amplification of the disease should it ever occur in this country," unquote. The agency further determined that the absence of compelling scientific evidence did not warrant any other protein feed ingredients other than specified proteins derived from mammalian tissues in ruminant animal feeds.

Darling International believes that the scope of the current rule sufficiently meets its stated objectives. Experts agree that feed safety must be built on risk-based scientific expertise. There is currently no compelling risk-based scientific evidence to support expanding the current feed ban to include other rendered materials, eliminating the exemptions for certain ruminant proteins previously determined to present no risk, such as blood and blood products, or to prohibit the feeding of rendered proteins provided by ruminant animals to other animal species. The current rule, surveillance program, import restrictions and marked differences in animal

production and feeding practices between the United States and European countries collectively make the likelihood of BSE occurring in the United States negligible. There is therefore no need to reopen the rule, and to do so is not scientifically justified nor warranted.

Rather than altering the current scope of the rule, the agency should consider addressing the way in which they follow and enforce the rule's parameters. Much in the current surveillance system could have been avoided had the FDA initially mandated the licensing of rendering facilities. At the time of the rule's inception, the agency would have known who the renderers were and what materials were handled and produced by each facility. The agency would have also been able to distinguish transfer stations that handle commingled materials for a processing facility and nonrendering plants, such as those handling used cooking oils to produce yellow grease and feed fats, and would have disregarded them from unnecessary inspection criteria. Many states currently issue state rendering licenses and

permits to operate. So additional federal licensing requirements would not have presented an undue burden provided clear guidelines were established. Licensing could also assist in advancing the rendering industry's credibility.

It is up to the rendering facility to determine what type of facility it will be, depending not only on the raw materials handled but the type of finished proteins it seeks to produce. Just because a facility handles exempt raw materials such as porcine or poultry meal does not mean that it is going to sell exempt material. Once the facility declares whether it will handle exempt raw material only, exempt and non-exempt raw materials in a manner consistent with the rule or commingled raw materials as restricted-use proteins, guidelines could be created to delineate the compliance parameters that must be adhered to.

At the same time, FDA compliance inspectors should be trained to be familiar with rendering facility operations and how such operations are performed under the rule. Too often the inspectors are unfamiliar

with how the facility operates or inspect for issues that are not covered by the rule, resulting in erroneous notations of noncompliance for that facility. FDA, APHIS and members of the rendering industry should consider jointly developing training and educational program that would set forth the rendering plant compliance inspection guidance for federal inspectors. Properly trained inspectors would further eliminate erroneous noncompliance citations and yield more accurate inspection data.

Penalties for noncompliance could be created ranging from warnings, monetary sanctions, injunctions and criminal penalties based on the particular licensing criteria that the FDA would establish.

When the FDA established the rule, it was noted that it would implement the vigorous enforcement program designed to prevent use of proteins derived from mammalian tissues in ruminant animal feed. It was the agency's intent to create a mechanism designed to limit the ability of the BSE to develop in this country. The rule provides this agency with the

ability to issue injunctions and post criminal penalties and seize, adulterated or misbranded product. However, to date enforcement activities for noncompliance with the rule has amounted to little than the issuance of warning letters. Moreover, the agency's compliance and inspection reports reflect inconsistent enforcement of the regulations established by the rule.

In order to ensure that the rule measures up to the FDA's intended goal, the FDA must be willing to diligently enforce compliance with the tenets of the rule in a consistent fashion. Instead of expanding the scope of the current rule to include more items subject to inconsistent surveillance and enforcement programs, the FDA should develop and adhere to a strong enforcement policy that not only mandates compliant behavior but also penalizes noncompliance accordingly. Clear and concise enforcement guidelines providing for monetary penalties for noncompliance must be established, along with provisions for other actions, such as mandatory recalls, cease-and-desist orders and suspension of

operations until noncompliant actions are corrected or abated.

If you're going to have inspectors out there, it is important that they be thoroughly and properly trained in all nuances of the regulatory requirements to ensure consistency and credibility in inspection activities. Matters that are not governed by the rule should not be part of the scope of the investigations unless there is a direct impact on compliance, such as the measures in place to prevent commingling of materials. Special attention should focus on familiarizing inspectors with the rendering process to avoid inconsistent inspections and the subsequent dissemination of misinformation related to the industry compliance to the rule.

There's a problem with sending out field staff to conduct inspections who view their role as simply information gatherers and they don't know the boundaries of what to inspect. The inspectors openly acknowledge that they know nothing about the rendering industry or the facilities that they inspect. They conduct the inspection of a company for

compliance to a rule that they themselves are uncertain how that operation is supposed to behave in order to be in compliance.

The inspectors are fact-finders who ask questions with an investigatory slant that may or may not be germane to the issues of compliance to the rule. All of the information generated by their investigation is sent up the line for someone else to interpret. This often includes the information gleaned that has no direct bearing on compliance. This type of information, otherwise irrelevant to compliance, is posted by the agency without proper interpretation and stimulates unnecessary and otherwise unwarranted public concern.

The inspection data posted by the FDA on their web site most show compliance or noncompliance for inspected facilities and disregard information that does not have any relevance to compliance. If the published inspection reports indicate whether or not a facility is compliant with the rule, the public's perception of compliance will improve.

It would also be extremely worthwhile for the agency to provide prompt

feedback to the managers of inspected facilities. Regarding their compliance status to the rule, currently many managers do not know the inspection results until after the agency has posted its findings on the internet. Increased communication with regulated parties will increase likelihood of compliance with the rules.

One issue of paramount concern that is outside the scope of the current rule is the status of the raw material itself. When the rule was first promulgated, dead ruminant animals and unprocessed ruminant-derived viscera, bone, fat trim, meat trim, blood and other animal products and by-products that are deemed to be inedible or unsuitable for human consumption were mainly handled and processed by the rendering industry. Yet over the years economic conditions and unforeseen marketing changes have negatively impacted the rendering industry, precipitated in part by the rule, coupled with rising international concern about BSE and pressure from Europe on the international community to adopt E.U. food safety principles and policies. As a result,

rendering facilities now charge for their services. This has prompted an increasing number of animal producers, locker plant operators, meat processors, and retail food chains to utilize alternative methods for the disposal of these raw materials. In short, the percentage of these raw materials that are collected and processed by the rendering industry is steadily declining. If it doesn't go to a rendering facility, do you know where this material will end up?

The origin and ultimate disposition of raw materials are not traceable when methods other than rendering are used. Rendering companies already possess the necessary infrastructure to allow for trace-back of raw materials and trace-forward of finished products. Only rendering companies are held accountable and required to document and maintain written records suitable for governmental agencies to trace raw materials back to their source and the finished products forward to the end user.

The current rule only prohibits the intended inclusion of proteins derived from

mammalian tissues in ruminant feeds. Ruminant materials that are disposed of through nonrendering means such as composting, landfill or on-site burial can still enter the food chain by a variety of means. The spread of composted materials of ruminant animal origin on land that is used for livestock grazing and/or hay production is permissible under the current rule. Domestic and wild animals, including ruminants, may have direct exposure to unprocessed ruminant raw materials that have been improperly buried, composted or placed in landfills. This is of particular concern because scientists believe that chronic wasting disease, a TSE affecting deer and elk, is transmitted when healthy animals are exposed to soil contaminated by the remains of an infected animal. It is believed that the soil can remain contaminated for decades. The unregulated use of nonrendering alternatives could lead to the amplification of the disease that the rule was implemented to prevent in the first place.

While incineration is a viable option for disposal of these raw materials, it is both costly and environmentally unsuitable.

Other alternatives to rendering for the disposal of raw materials, such as composting, on-site burial or landfills, do not provide adequate biosecurity with respect to BSE as well as other infectious diseases. The best means of attaining and maintaining biosecurity is to regulate the disposition of all raw materials of ruminant origin by having licensed rendering facilities collect, transport and process them in order to limit exposure of domestic and wild ruminant animals to these raw materials. The regulation of these raw materials can be established independent of and in addition to the present feed rule.

In conclusion, before the FDA expands the scope of the rule and/or removes any exempt products from the list, in the absence of compelling scientific evidence, to do otherwise the agency should make certain that it has done everything it can do under the current terms of the existing rule.

The agency should focus on how to improve performance and compliance under the present rule parameters. There should be better-developed and concise surveillance and

enforcement guidelines established by the agency, including the development and implementation of an appropriate penalty schedule that would mandate compliance. Federal compliance inspectors must be properly trained both in nuances of the rule and how the rule applies to the industry that they inspect. Establishment of federal licensing guidelines would further assist the agency in this direction.

Most of all, the agency must address the need to regulate the raw materials from the outside by requiring that only licensed renderers collect, transport and process the materials. To permit continued disposal of these materials through nonrendering means undermines the intent of the rule; that is, to prevent the establishment and amplification of the disease should it ever occur in this country.

Thank you.

DR. LUMPKIN: Thank you, Mr. Frish.

Are there questions?

(No response.)

DR. LUMPKIN: Thank you again.

The next speaker is Mr. Kevin Custer. He vice president of technical services for American Proteins, Incorporated, in Cumming, Georgia.

MR. CUSTER: I'd like to thank the agency for the opportunity to make comments on this issue. Today I am representing American Proteins, a renderer in Georgia and Alabama, processed poultry by-products. I have a brief statement which I will read and will present for the record.

The final rule established at Section 589.2000 has the stated objective to prevent the establishment and amplification of the agents of bovine spongiform encephalopathy in the United States cattle through feed and thereby help minimize any risks from such agents to animal or human health. The objective has been and is being met.

In addition to the rule, other safeguards are in place to meet the objective of the rule. APHIS/USDA introduced import restrictions very soon after the initial Great Britain diagnosis, and over the years has added

to those restrictions as warranted. FSIS/USDA has submitted over 12,000 cattle from nearly every state and Puerto Rico for examination with no evidence of BSE or TSE found.

In addition to government initiatives, several industry programs have been initiated, most notably third-party certification administered by Cooke and Thurber for rendering and animal protein blending facilities. A compliance rate of 98 percent was noted, two percent difference from a hundred percent. It's reported there are facilities yet to be inspected.

In summary BSE does not exist in the United States. Broadening the list of animal proteins prohibited is not warranted by scientific scrutiny.

And I would again like to thank the agency for this opportunity. If there's any questions, I'd be happy to answer them.

DR. LUMPKIN: Thank you, Mr. Custer.

Are there any questions from the panel?

(No response.)

DR. LUMPKIN: Thank you, sir.

The next speaker is Mr. Dennis Griffin. He is chairman of the Griffin Industries, Incorporated, in Cold Spring, Kentucky.

MR. GRIFFIN: Thank you.

Ladies and gentlemen, I'm here to submit my testimony today in response to your agency's request for comments on the possibility of opening up the regulation that was then listed in Federal Register on October 5th, 2001.

I'm speaking today on behalf of our family business, Griffin Industries, which has been in the rendering business for over 58 years. We are based in northern Kentucky and serve many animal agricultural members throughout the midwest, the southeast and the southwest part of our country. Our company is in full compliance of the ruminant-to-ruminant food regulation and HACCP programs in all its processing facilities, and it is participating in the Animal Protein Producers third-party certification program, which, with increased plant and procedure inspections, has helped bolster FDA's inspection program.

I wish to begin my comments by saying that BSE has not been detected in the United States. It has been over fifteen years since the first known case of BSE was discovered in the United Kingdom, with many thousands of confirmed cases throughout Europe. The disease has been a European-domiciled disease, with only one other case reported in other sections of the world, but it had ties with European suppliers.

We strongly support the existing action taken by your agency in June of 1997 to build a firewall against BSE and see no reason to change or modify CFR 589.2000.

We as Americans have a good program in place, and, with continued awareness and enforcement by your agency, will provide our consumers the continued confidence they need in U.S. meat products.

The highest awareness level in food safety history has been created by actions taken by the agency and by industry such as the ruminant-to-ruminant feed ban, the ongoing testing of suspect animal brain, which is currently approaching sixteen thousand animals that have been tested. The industry's

third-party inspection program has our industry participation of over 98 percent -- unheard of in past practices.

Being in this industry for over 40 years, I've never experienced such an effort on the part of animal agriculture, and especially our industry, and working so closely with your agency in this precautionary program against this foreign disease.

Since the discovery of the first BSE case in 1986, scientists still do not have clear evidence for the cause of BSE or the new version in humans, or that BSE has ever crossed species boundaries. There are new theories and hypotheses developing throughout the world as more research takes place. And with that, I'm sure that there will be a true cause of BSE discovered in the near distant future.

In closing, we support working with the current regulation and increased effort for enforcing it. Changing the rules sends a wrong message to consumers and protein users domestically as well as internationally that something is wrong with our current efforts.

And this is clearly not the case. If it isn't broken, don't try to fix it. Remember, we have not discovered any BSE in the United States, and with fifteen years behind us without any detection, further changes to our safety measures are unwarranted.

Thank you for giving us the opportunity to respond. And if you all have any questions...

DR. LUMPKIN: Thank you, Mr. Griffin.

Any questions from the panel?

(No response.)

DR LUMPKIN: Thank you, sir.

The next speaker this morning is Mr. David Kaluzny from Kaluzny Brothers, Incorporated, Joliet, Illinois.

MR. KALUZNY: Thank you, Mr. Chairman.

Kaluzny Brothers is a 55-year-old independent rendering firm serving the northern half of Illinois, Southern Wisconsin and Northwest Indiana. We process bones, fat, offal and hides from both ruminant and nonruminant animals, as well as various

greases. I will refer to my questions as they were numbered within the request for data.

Number 1. We do not see any need to change the enforcement activities of the agency. Rather, more importantly, we see a need to improve the accuracy and completeness of the reporting of the agency's inspections. We feel this reporting has done more to cause concern amongst the public than any actual noncompliance with the rule that has actually occurred.

Number 2. This question really asked: Is the rule doing its job? And we feel yes, it is. Its intent was to create an additional firewall around our beef industry. As we sit here now, we do not have BSE in this country. I dare say we never will. This disease first emerged fifteen years ago and has never been found in this country. And today 99.999 percent of all cases have been confined to Europe; 99.9 percent in England, the other 0.99 percent in the rest of Europe and only one case in Japan.

Furthermore, as a country we've been vigorously looking for signs of this disease by examining thousands of cattle breeds

every year. We have never found BSE. It seems to me, again, the rule is working.

The ban should not be broadened in any way either. It works now, and, more importantly, there is no new scientific evidence that has come forth in the past four years that in any way would suggest that we make any changes.

Number 4. The FDA should not require dedicated facilities for the production of animal feeds containing mammalian proteins. The current rule already addresses the issue of prevention of commingling quite adequately. Procedures and controls are already in place and being used to prevent commingling and contamination in rendering facilities.

Number 5. The agency should not require dedicated transportation for animal feed containing mammalian proteins. This issue as it relates to commingling or cross-contamination is, again, already addressed within the rule and, at the same time, is currently not a problem. To require such at this time would only needlessly add to costs while not adding to any further protection of

animal feed.

Number 6. We would not oppose FDA licensing of renderers as it relates to the current rule in effect, CFR 589.2000.

Number 7, the FDA should not revoke or change any of the current exclusions allowed for in the rule. There is, again, no new scientific evidence that has come forth that would even remotely justify any such move.

Number 8. The FDA does not need to add to the list of prohibited materials and language relating to poultry litter. The rule addresses protein from mammalian tissue, and, as such, already addresses this issue. Further elaboration or definition would only serve to confuse.

Number 9. No, the exemption should not be removed for pet food either. It is not normally fed to animals for human consumption.

Number 10. The current recordkeeping requirement, in light of annual and sometimes biannual inspections, seems adequate at one year. If, however, the agency can see a need for further data beyond a year,

we would support such a move if it makes the rule any better.

Number 11. The FDA should not change the rule to require labeling of the specific type of mammal used in the production of a specific protein. Such a need is nonexistent in light of the requirement to label "Do not feed to cattle or other ruminants." Beyond that, this would only serve to confuse feeders, feed mills, blenders, cattlemen and nutritionists who already have a fully understood list of feed ingredients they work with and that are used nationwide.

Number 12. The current cautionary statement should stand as is. It is clear, to the point and well understood. It was designed that way. If, however, the agency knows of individuals feeding deer, elk or bison with prohibited proteins, I would support such a change. However, I don't know of any with such animals feeding them any animal proteins, and I know of no such commercially available feed for that purpose either.

As far as I know, number 13, there is no currently available accurate and

efficient analytical method for detecting prohibited mammalian protein in feeds.

Number 14. I see no need here for any more enforcement authority; rather, an assurance that all inspectors, state and federal, are working, quote, unquote, out of the same songbook, so to speak would help keep uniform assessment across the country.

Number 15. Private certification programs have worked tremendously in the rendering industry. Through APPI we have engaged the use of Cooke & Thurber of Madison, Wisconsin, to certify, plant by plant, renderer compliance with the rule, and therefore intent and actual manufacture of safe feed ingredients. We had the honor of being the first plant to go through the compliance audit, and we were proud to do so. Just as important, third-party audits also give the agency the ability to point to an outside entity that can verify compliance with the rule.

Number 16. Regarding the importation of feed ingredients, the restrictions should be based on the incidence or non-incidence of BSE in the country of origin.

Number 17. Regarding what additional measures could be taken to further guard against BSE, I offer the following. I will not offer any views on preventing CJD or variant CJD as there is still no known cause for such, and as recent as two weeks ago scientists in Great Britain are claiming that variant CJD could not be caused by eating BSE-tainted beef.

But with regards to BSE itself, four and a half years ago, in offering comments before the agency on the then proposed rule, I called for an all-out effort to eliminate our country's only known farm animal TSE: Scrapie. Quote, "Therefore, let us make an all-out effort to eliminate all scrapie, our only known TSE, from the U.S. Let us start with an immediate destruction of all scrapie flocks and a total indemnification program for the owners. And if TSE elimination is that important, let us complete that phase in 12 months. Let us rid ourselves of that agent all together.

"Australia and New Zealand did it years ago and they have far more sheep than we have in the U.S. Why haven't we?"

That was four and a half years

ago I said that.

To that, today I would add that we could certainly import enough scrapie-free sheep from both Australia and New Zealand to aid in the indemnification process at the same time.

Secondly, with regard to additional measures, I would like to point out to the agency a growing tendency within various states to allow for nonrendering disposal of animal by-products. Here I refer to composting and landfilling. These methods serve to remove this material from biosecure rendering and at the same time remove it from the traceability offered by the rendering industry in conjunction with the rule.

In summary, the current rule as it stands is good, and even more importantly, it is working. There is no scientific reason to change any of the parameters of the rule in any way. No new scientific elements have come to light in the past four years.

Furthermore, we do not have BSE in this country. And again, I dare say, we never will. Our cattle are now even more protected than we have ever had them before from

contracting BSE. Let's concentrate on eliminating our TSE of scrapie and eliminate people's fears of our cattle succumbing to BSE through scrapie, as unfounded as that may be.

Thank you for your time and consideration.

DR. LUMPKIN: Thank you, Mr. Kaluzny.

Any questions?

(No response.)

DR. LUMPKIN: Thank you, sir.

Our next speaker is Mr. Gerald Smith. He is president of Value Proteins, Incorporated, in Winchester, Virginia.

MR. SMITH: Good morning. I'm Gerald F. Smith, Jr., president of Valley Proteins, Incorporated, Winchester, Virginia.

Founded in 1949, Valley Proteins and its subsidiary, Carolina By-Products, is one of the four largest independent recyclers of animal by-products and waste cooking oils in the United States. Our firm operates 22 total facilities, including 14 manufacturing plants for recycling animal by-products located along the eastern seaboard

and southwest region of the United States. We employ over 1300 individuals and operate a fleet of 450 trucks. In the year 2000 we recycled over 3.4 billion pounds of waste materials which was collected from over 65,000 restaurants, supermarkets, farmers and animal and poultry processing facilities located in 17 states.

Our organization fully supports FDA Regulation Section 589.2000 enacted in 1997. The U.S. rendering industry took a leadership role in promoting the fire walls around the U.S. cattle industry which resulted from this regulation. In fact, our industry forfeited marketplace for twelve to eighteen percent of our animal protein products when this regulation was enacted.

When enacted in 1997, this regulation was based on the best scientific data then available and on the recommendations of the World Health Organization. All exemptions to this regulation are also based on the best scientific data available in 1997. Since 1997, BSE has declined significantly in the United Kingdom, but new cases and increased incidences of BSE have occurred throughout the remainder,

and most recently in Japan. What has not changed since 1997 is that the U.S. remains BSE-free. These new and increased cases outside the U.K. can be attributed to the export of infected animals from the U.K. and to meat and bone meal which was produced from such infected animals. While it is not scientifically conclusive that the spread of BSE was caused by meat and bone meal derived from infected animals, there certainly has been a strong correlation to the consumption of this product.

First, I believe that if BSE were to occur in the United States, it would almost certainly be through the importation of infected animals, animal products or animal by-products. The U.S. government has a duty to increase funding which will allow the FDA, the USDA to protect our country where this disease will almost certainly enter our country: At our ports or borders. With our current concerns over bioterrorism, it is more important than ever that the U.S. be extremely vigilant to make certain that diseases and substances which can harm our human and livestock populations are detected and stopped before they enter our

country.

Second, I believe we have an adequate program of surveillance for BSE, and if this disease were to occur in the United States that it would be detected at the earliest possible time. Our USDA is and has been doing an excellent job of surveillance for BSE. We have tested a greater population of animal brains than that suggested by the World Health Organization for the size of our livestock population. Even more important is that USDA has stepped up surveillance at facilities that receive downer cattle, since this is by far the most likely point for an infected animal to enter our food and/or our food chain.

Third, while I believe we have very adequate firewalls to prevent BSE from entering our food and feed chain and prevent amplification of this disease should an infected animal be found in our country, these regulations are only effective if thoroughly enforced. Our company has entered into a voluntary third-party certification because we believe that 100 percent of our facilities must be in compliance with this regulation. I

support additional funding which would allow FDA each year to inspect an adequate number of dairy farms, cattle feeding establishments, feed compounding facilities and rendering facilities to assure compliance with this regulation. The E.U. and especially the U.K. had adequate regulations. What the Europeans did was fairly to adequately enforce these regulations, and as a result, the European consumers lost faith in both their food industry and their governments. Let us make sure we don't follow their example.

In conclusion, I fully support the FDA's regulation Section 589.2000 which restricts the feeding of ruminant derived by-products to ruminants. I am, however, opposed to reopening this rule, to expanding this rule, or to revoking the exemption for any products which are not exempted by this rule, since I believe any change to this regulation should be based on sound scientific data. Such scientific data has not changed since this rule was enacted in 1997.

I believe surveillance for BSE within the United States is adequate but must be a made a priority for funding so that USDA may